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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,211	10/30/2006	Bakulesh Mafatlal Khamar	43939	9175
26486	7590	12/09/2010	EXAMINER	
BURNS & LEVINSON, LLP 125 SUMMER STREET BOSTON, MA 02110				SWARTZ, RODNEY P
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE			DELIVERY MODE	
12/09/2010			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@burnslev.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,211	KHAMAR, BAKULESH MAFATLAL	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7September2010, 3December2010.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 22-29,32,36-43 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 36-43 and 48 is/are allowed.
- 6) Claim(s) 22-29,32 and 45-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>12/10</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**
2. Applicant's response to Office Action, received 7 September 2010, is acknowledged. Claims 22, 32, 36, 37, 38, 42, 45, 46 and 47 have been amended. Claims 34 and 49-54 have been cancelled.
3. Applicant's Power of Attorney, received 3 December 2010, is acknowledged.
4. Claims 22-29, 32, 36-43 and 45-48 are pending and under consideration.

Rejections Moot or Withdrawn

5. The rejection of claim 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is moot in light of the cancellation of the claim.
6. The rejection of claims 36-43 and 45 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in light of the amendment of the claims to depend from claim 48.

Rejections Maintained

7. The rejection of claims 22-27 and 32 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for reasons of record.

Applicant argues that extraction processes for bacteria are known and it is not implausible to those skilled in the art that those methods and resultant products as applied to providing a medicament would not be effective against obstructive lung diseases where heat killed and sonicated versions of *Mycobacterium* w have been shown effective.

The examiner has considered applicant's argument, but does not find it persuasive for the reasoning put forth in the original rejection. The lack of enablement is not for simply preparing extracts, but utilizing said extracts in a method of treating, managing or preventing

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disease of the lungs. As put forth in the original rejection explanation, the only extracts which indicate such treatment are extracts produced utilizing the solvents chloroform, ethanol, methanol and acetone or utilizing the enzyme liticase. These limited examples do not provide sufficient support that all solvents listed or all enzymes listed result in extracts that fulfill the required methods of treatment, management or prevention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is a treating, managing or preventing obstructive lung disease by administration of a composition comprising heat killed "whole cell" *Mycobacterium w*.

Instant claim 45 depends from claim 48. Claim 45 is unclear because claim 48 restricts the composition to heat killed "whole cells", but claim 45 now recites that the *Mycobacterium w* may be sonicated or solvent extracts of *Mycobacterium w*. It is unclear how a whole cell may also be a sonicate or extract form.

9. Claims 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent from a cancelled claim.

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10. Claims 28, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

Conclusion

11. Claims 22-29, 32 and 45-47 are rejected. Claims 36-43 and 48 are allowed.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Larry Helms, at (571)272-0832.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

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Primary Examiner, Art Unit 1645

December 6, 2010

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